Application No.: 09788,126

Amendment dated September 10, 2003 Reply to Office action of March 10, 2003

## Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

- 1. (original) A formulation having particles comprising, by weight, approximately 60% DPPC, approximately 30% insulin and approximately 10% sodium citrate.
- 2. (original) A formulation having particles comprising, by weight, approximately 40% DPPC, approximately 50% insulin and approximately 10% sodium citrate.
- 3. (original) The formulation of Claim 1, wherein the particles comprise a mass of from about 1.5 mg and about 20 mg of insulin.
- 4. (currently amended) The formulation of Claim 1, wherein the particles <u>are placed</u> in a receptacle and comprise a mass of about 1.5 mg of insulin per receptacle.
- 5. (currently amended) The formulation of Claim 1, wherein the particles <u>are placed</u>
  in a receptacle and comprise a mass of about 5 mg of insulin per receptacle.
- 6. (original) The formulation of Claim 1, wherein the particles comprise a dosage of insulin of between about 42 IU and about 540 IU.
- 7. (original) The formulation of Claim 6, wherein the particles comprises a dosage of insulin of about 42 IU.
- 8. (original) The formulation of Claim 6, wherein the particles comprise a dosage of insulin of between about 84 IU and about 294 IU.

- 9. (original) The formulation of Claim 8, wherein the particles comprise a dosage of insulin of between about 155 IU and about 170 IU.
- 10. (original) The formulation of Claim 1, wherein the particles have a tap density less than about 0.4 g/cm<sup>3</sup>.
- 11. (original) The formulation of Claim 10, wherein the particles have a tap density less than about 0.1 g/cm<sup>3</sup>.
- 12. (original) The formulation of Claim 1, wherein the particles have a median geometric diameter of from between about 5 micrometers and about 30 micrometers.
- 13. (original) The formulation of Claim 1, wherein the particles have an aerodynamic diameter of from about 1 micrometer to about 5 micrometers.
- 14. (original) The formulation of Claim 13, wherein the particles have an aerodynamic diameter of from about 1 micrometer to about 3 micrometers.
- 15. (original) The formulation of Claim 13, wherein the particles have an aerodynamic diameter of from about 3 micrometers to about 5 micrometers.
- 16. (original) The formulation of Claim 1, wherein the particles further comprise an amino acid.
- 17. (original) The formulation of Claim 16, wherein the amino acid is leucine, isoleucine, alanine, valine, phenylalanine or any combination thereof.

- 18. (original) A method for treating a human patient in need of insulin comprising administering pulmonarily to the respiratory tract of a patient in need of treatment, in a single, breath actuated step an effective amount of particles comprising by weight, approximately 60% DPPC, approximately 30% insulin and approximately 10% sodium citrate, wherein release of the insulin is rapid.
- 19. (original) A method for treating a human patient in need of insulin comprising administering pulmonarily to the respiratory tract of a patient in need of treatment, in a single, breath actuated step an effective amount of particles comprising by weight, approximately 40% DPPC, approximately 50% insulin and approximately 10% sodium citrate, wherein release of the insulin is rapid.
- 20. (original) The method of claim 18, wherein the patient in need of treatment has diabetes mellitus.
- 21. (original) The method of Claim 18, wherein the particles have a mass of from about 1.5 mg and about 20 mg of insulin.
- 22. (original) The method of Claim 18, wherein the particles comprise a mass of about 1.5 mg of insulin per receptacle.
- 23. (currently amended) The method of Claim 18, wherein the particles are placed in a receptacle and comprise a mass of about 5 mg of insulin per receptacle.
- 24. (currently amended) The method of Claim 18, wherein the particles are placed in a receptacle and comprise a dosage of insulin of between about 42 IU and about 540 IU.

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- 25. (original) The method of Claim 24, wherein the particles comprises a dosage of insulin of about 42 IU.
- 26. (original) The method of Claim 24, wherein the particles comprise a dosage of insulin of between about 84 IU and about 294 IU.
- 27. (original) The method of Claim 26, wherein the particles comprise a dosage of insulin of between about 155 IU and about 170 IU.
- 28. (original) The method of Claim 18, wherein the particles have a tap density less than about 0.4 g/cm<sup>3</sup>.
- 29. (original) The method of Claim 28, wherein the particles have a tap density less than about 0.1 g/cm<sup>3</sup>.
- 30. (original) The method of Claim 18, wherein the particles have a median geometric diameter from about 5 micrometers and about 30 micrometers.
- 31. (original) The method of Claim 18, wherein the particles have an aerodynamic diameter of from about 1 micrometer to about 5 micrometers.
- 32. (original) The method of Claim 31, wherein the particles have an aerodynamic diameter of from about 1 micrometers to about 3 micrometers.
- 33. (original) The method of Claim 31, wherein the particles have an aerodynamic diameter of from about 3 micrometers to about 5 micrometers.
- 34. (original) The method of Claim 18, wherein administering the particles pulmonarily includes delivery of the particles to the deep lung.

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- 35. (original) The method of Claim 18, wherein administering the particles pulmonarily includes delivery of the particles to the central airways.
- 36. (original) The method of Claim 18, wherein administering the particles pulmonarily includes delivery of the particles to the upper airway
- 37. (original) The method of Claim 18, wherein the particles further comprise an amino acid.
- 38. (original) The method of Claim 37, wherein the amino acid is leucine, isoleucine, alanine, valine, phenylalanine or any combination thereof.
- 39. (original) A method of delivering an effective amount of insulin to the pulmonary system, comprising:
  - a) providing a mass of particles comprising by weight, approximately 60% DPPC, approximately 30% insulin and approximately 10% sodium citrate; and
  - b) administering via simultaneous dispersion and inhalation the particles, from a receptacle having the mass of the particles, to a human subject's respiratory tract, wherein release of the insulin is rapid.
- 40. (original) A method of delivering an effective amount of insulin to the pulmonary system, comprising:
  - a) providing a mass of particles comprising by weight, approximately 40% DPPC, approximately 50% insulin and approximately 10% sodium citrate; and
  - b) administering via simultaneous dispersion and inhalation the particles, from a receptacle having the mass of the particles, to a human subject's respiratory tract, wherein release of the insulin is rapid.

- 41. (original) The method of Claim 39, wherein the mass of particles is from about 1.5 mg and about 20 mg of insulin.
- 42. (currently amended) The method of Claim 39, wherein the particles are placed in a receptacle and the mass of said particles comprises about 1.5 mg of insulin per receptacle.
- 43. (currently amended) The method of Claim 39, wherein the particles are placed in a receptacle and the mass of said particles comprises about 5 mg of insulin per receptacle.
- 44. (original) The method of Claim 39, wherein the mass of particles comprises a dosage of insulin of between about 42 IU and about 540 IU.
- 45. (original) The method of Claim 44, wherein the mass of particles comprises a dosage of insulin of about 42 IU.
- 46. (original) The method of Claim 44, wherein the mass of particles comprises a dosage of insulin of between about 84 IU and about 294 IU.
- 47. (original) The method of Claim 46, wherein the mass of particles comprises a dosage of insulin of between 155 IU and about 170 IU.
- 48. (original) The method of Claim 39, wherein the particles have a tap density less than about 0.4 g/cm<sup>3</sup>.
- 49. (original) The method of Claim 48, wherein the particles have a tap density less than about 0.1 g/cm<sup>3</sup>.

- 50. (original) The method of Claim 39, wherein the particles have a median geometric diameter of from about 5 micrometers and about 30 micrometers.
- 51. (original) The method of Claim 39, wherein the particles have an aerodynamic diameter of from about 1 micrometer to about 5 micrometers.
- 52. (original) The method of Claim 50, wherein the particles have an aerodynamic diameter of from about 1 micrometer to about 3 micrometers.
- 53. (original) The method of Claim 50, wherein the particles have an aerodynamic diameter of from about 3 micrometers to about 5 micrometers.
- 54. (original) The method of Claim 39, wherein delivery to the pulmonary system includes delivery to the deep lung.
- 55. (original) The method of Claim 39, wherein delivery to the pulmonary system includes delivery to the central airways.
- 56. (original) The method of Claim 39, wherein delivery to the pulmonary system includes delivery to the upper airways.
- 57. (original) The method of Claim 39, wherein the particles further comprise an amino acid.
- 58. (original) The method of Claim 57, wherein the amino acid is leucine, isoleucine, alanine, valine, phenylalanine or any combination thereof.
- 59. (original) The formulation of Claim 1, wherein the particles further comprise a low transition temperature phospholipid.

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60. (original) The method of Claim 18, wherein the particles further comprise a low transition temperature phospholipid.